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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,860	11/29/2001	Geert Maertens	2551-69	4135

23117 7590 10/19/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,860	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17 and 20-43* is/are pending in the application.

4a) Of the above claim(s) *27-35 and 41-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,20-26,36-39 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 15-17, and 20-43 are pending.

Response to Amendment

This is a response to the amendment, paper No. 13, filed 07/17/04. Claims 20-29, 31, 33-37 and 40-42 have been amended. New claim 43 is added. Claims 15-17, and 20-43 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 07/17/2004 was filed after the mailing date of the first Office Action on 01/15/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

2. Upon reconsidering the pending claims after newly submitted amendment, claim 17 is rejoined with the elected group I. Because there is no new ground compared with the previous Office Action, the Office Action is still made Final.

Specification

1. The specification is still objected to as failing to provide proper antecedent basis for the claimed subject matter "E1s" in claim 20 on the same ground as stated in the previous Office Action.

2. Applicants argue that the term Els is described throughout the present application, the claimed priority applications and was well known in the art, therefore, no need for describing the recited E1s is required. Applicants' augment has been fully considered; however, applicants do not point out where the recitation of E1s is in the specification. While the priority document has

recited or described this term, a description of this molecule in the current specification is still required.

Claim Rejections - 35 USC § 112

3. Claims 15, 16-17, 20-26, 36-39, 40 and 43 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action.

1. Claim 15 is still rejected for failing to define what is the claimed product used for performing the claimed function. Applicants transverse the rejection and submit that the art has failed to demonstrate the therapeutic efficacy of any HCV vaccine and that the applicants demonstration of the same should afford broad protection.

2. Applicants' argument has been fully considered; however, it is not persuasive because the rejection is not because the claim reads broadly, it is because the claim is unclear about what claimed product is since the claim only describes the intended use, but not what it is comprised of as required by the MPEP cited in the previous Office Action.

3. Applicant's argument also does not comply with 37 CFR 1.111(c) because is does not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made.

4. Regard the 112 2nd paragraph rejection for recitation of "a part thereof", Applicants argue that in view of the present disclosure, one of ordinary skill in the art will appreciate that the definition of HCV envelope protein includes the "part thereof" as being at least one epitope of either the E1 or the E2 region, in the present case the E1 region. Therefore, the recitation " a part thereof" therefore is submitted to be sufficiently clear.

5. Applicants' argument has been fully considered; however, it is not persuasive because the argument does not comply with 37 CFR 1.111(c), especially in view of the prior art rejections, because it does not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited in the previous office Action. Further, they do not show how the amendments avoid such references or objections.

6. Therefore, the rejections are maintained.

Double Patenting

7. Claims 15, 16, 17, 18, 21-26, 36-39, 40 and 43 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 16 and 21 of U.S. Patent No. 6, 635,257 B1 and the copending application No. 09/995, 791on the same ground as stated in the previous Office Action.

8. Because applicants do not address these issue and point out the errors for the rejections, the rejections are maintained.

Claim Rejections - 35 USC § 102

9. Claims 15, 16, 17, 20-26, 36, 37, 38, 39, 40, 43 are still rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (WO 96/04385A2) on the same ground as stated in the previous Office Action.

10. Applicants traverse and submit that claims 15 and 16 are rejected under 112 1st paragraph, therefore the claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.

11. Applicants' argument has been fully considered; the 112 1st paragraph issue has been removed in view of applicants' argument. The rejected on claims 15, 16, 17, 20-26, 36, 37, 38, 39, 40, 43 are therefore, maintained.

12. Claims 15, 16, 36, 37, 40 and 43 are still rejected under 35 U.S.C. 102(b) as being anticipated by Choo et al. (P.N.A.S. USA, 1994, Vol. 91, pp. 1294-1298) on the same ground as stated in the previous Office Action.

13. Applicants traverse and submit that since claims 15 and 16 are rejected under 112 1st paragraph, the claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."

14. Applicants' argument has been fully considered; the 112 1st paragraph rejection has been removed in view of applicants' argument. Claims 15, 16, 36, 37, 40 and 43 are therefore, still anticipated by the cited prior art.

15. Claims 15, 16, 36, 37, 40 and 43 are still rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (Prospects for prophylactic and therapeutic hepatitis C virus vaccines. Princess Takamatsa Symp. 1995, Vol. 25, pp. 237-243).

16. Applicants traverse and submit that since claims 15 and 16 are rejected under 112 1st paragraph, the claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."

17. Applicants' argument has been fully considered; the 112 1st paragraph rejection has been removed in view of applicants' argument. Claims 15, 16, 36, 37, 40 and 43 are therefore, still anticipated by the cited prior art.

18. Claims 15, 16, 36, 37, 40 and 43 are still are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (Proceeding of IX Triennial International Symposium on viral hepatitis and liver disease, Rizetto Purcell, gerin, Verme, eds. Edizioni Minerva Medica, Italy, 1997, pp. 656-657).

19. Applicants traverse and submit that since claims 15 and 16 are rejected under 112 1st paragraph, the claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."

20. Applicants' argument has been fully considered; the 112 1st paragraph rejection has been removed in view of applicants' argument. Claims 15, 16, 36, 37, 40 and 43 are therefore, still anticipated by the cited prior art.

21. Claims 15, 16, 36, 37, 40 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al. (US Patent No. 5,670,152A).

22. Applicants traverse and submit that since claims 15 and 16 are rejected under 112 1st paragraph, the claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."

23. Applicants' argument has been fully considered; the 112 1st paragraph rejection has been removed in view of applicants' argument. Claims 15, 16, 36, 37, 40 and 43 are therefore, still anticipated by the cited prior art.

24. For all of above rejection, Applicants further argue that the cited references by Choo et al, (1994), Weiner et al., and Houghton et al., which are similarly to each other, failed to establish the disclosed compositions being used as a therapeutic composition. Therefore, they cannot anticipate the claimed invention. Applicants' argument has been considered; however, it is not found persuasive because the compositions disclosed by the cited references are all drawn to the compositions comprising a HCV E1 envelope protein or fragment thereof, which are the same to the claimed composition, especially the broadly scope of claim 15 is drawn to any composition.

25. Moreover, the recitation of "therapeutic vaccine" in claim 15 and 16 (recitation of "a part thereof") only belongs to a preamble language, which only describes an intended use of the composition. Applicants are reminded if an intended use is recited in a claim, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the cited references alleged by Applicants demonstrate the HCV immunogenic compositions that are able to induce both humoral and cellular immune responses. Especially in view of the disclosures of the specification, which defines the therapeutic vaccine composition as the same composition as an immunogenic or vaccine composition that may bc used for treating HIV infection purpose (See line 8-13 on page 9). Moreover, applicants argued in the response regarding the enablement issue that the criteria of the claimed therapeutic vaccine is a property of stimulating T cells by the HCV envelope proteins and fragments thereof, but not a protective immunity against HCV infection. The compositions taught by the prior arts meet the criteria defined by the current application as s therapeutic composition. The claimed invention is therefore, anticipated by the cited references. The rejections are maintained.

Conclusion

No claims are allowed.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
10/07/2004

JAMES HOUSEL 10/15/04
SUPERVISORY PATENT EXAMINER
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